

P20918.A01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Fred ZACOUTO et al.

Group Art Unit: 3738

Appln. No. : Unknown
(Continuation of US application 09/200,855)

Examiner: B. Snow

Filed : Concurrently herewith

For : SKELETAL IMPLANT

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Washington, DC 20231

Sir :

Applicants respectfully request that the Examiner not issue an Office action until after three months from the filing date of this continuation application. Applicants are in the process of preparing additional revisions to the specification and a new set of claims which will replace the claims originally filed (i.e., claims 1-9) and expect to file the same within this three month period. Should the Examiner wish to examine this application sooner, he is invited to contact the undersigned in order to have the additional Preliminary Amendment filed earlier.

Prior to calculating the filing fee and prior to the examination of the above-identified patent application, the Examiner is respectfully requested to enter the following amendments

which incorporate amendments made in the parent application:

IN THE SPECIFICATION

Please replace the paragraphs starting on page 63, line 31 to page 65, line 24 with the following paragraph (see the Appendix for changes):

--Figure 64 shows a transverse cross section of an implant in a refined embodiment of the invention.

This implant 1' includes two end pieces 51' and 52' in the shape of a dolphin's head, having at their outermost parts holes or eyelets 53' and 54' through which it is possible to engage pedicle screws whose heads can be fixed rigidly in the area of the holes 53', 54'. Alternatively, these holes can be arranged in such a way as to permit an articulation of the head of the pedicle screw and thus an angular displacement between the end element and the screw which it bears.

Arranged between the two end pieces 51' and 52' there is a third piece 55' which is movable relative to the two ends. The piece 55' has a stirrup shape, of which one of the branches 56' supports a metal bellows 57' in a leaktight manner, the free end of which bellows is fixed in a leaktight manner against a piece 58' which is able to slide relative to the stirrup 55' and bears, in the manner of a journal, by virtue of a securing ring 45', but axially nonmovable relative to the piece 58', a threaded rod 59' which passes through a

P20918.A01

complementary tapped hole of the second branch 60' of the piece 55'. It will thus be appreciated that when the deformable element constituted by the bellows 57' deforms, the thus provoked axial displacement of the rod 59' integral with the upper end 52' entrains the rotation of this rod 59' in the fixed nut formed in the branch 60', and consequently a simultaneous movement of translation and rotation of the end piece 52' relative to the piece 60'.

Arranged inside the end piece 51' is a leaktight cavity 61' which serves as a high-pressure chamber and in which there is a bellows 62' which is hermetically sealed and in which a vacuum has been established. The stiffness of this bellows, however, is sufficient to ensure that it tends spontaneously to deploy and increase in volume even when it is surrounded by high pressure prevailing in the chamber 61'. The chamber 61' communicates via a nondeformable conduit 63' with the inside of the metal bellows 57' by way of a high-pressure valve 64' lodged in the branch 56'. This valve 64' has a tubular slide of soft iron 65' which is normally held back by a spring in the position closing off the passage towards the bellows 57'. It will be appreciated that when the plunger core 65' is brought into a position of opening counter to the valve spring, liquid at high pressure in the chamber 61' will run along the conduit 63' and enter the bellows 57'. The high pressure in the chamber 61' is maintained by the concomitant deformation of the sealed bellows 62'. This inflow of liquid provokes the displacement of the piece 58' towards the branch 60' and, consequently,

P20918.A01

the distraction and rotation of the end piece 52' relative to the central piece 55'.

The inside of the bellows 57' also communicates, by way of a low-pressure valve 66' equipped with a plunger core identical to the core 65' situated in the piece 58', with the volume 67' surrounding the various pieces contained inside the deformable impermeable sleeve 68', at the two ends of which the ends of the pieces 51' and 52' emerge, this volume 67' forming the low-pressure volume. It will be appreciated that when the valve 66 is opened, liquid contained in the bellows 57' will exit and spread through the low-pressure volume 67', thus permitting a retraction or compression of the bellows 57' and a simultaneous rotation of the piece 52' in the opposite direction.

The high-pressure reservoir 61 is recharged by way of a metal bellows 69' which is of a diameter substantially smaller than that of the bellows 57' and which is interposed between the pieces 51' and 55'. When the pieces 51' and 55' move away from each other, this bellows 69' expands and aspires liquid from the low-pressure chamber 67' by way of a nonreturn valve 70'. By contrast, when the pieces 51' and 56' close together, the high pressure generated in the bellows 69' causes liquid at very high pressure to enter the high-pressure chamber 61' by way of a nonreturn valve 71'.

It is not necessary for the deformation of the bellows 69' to be of a great amplitude; on the contrary, it is preferable for the gap between the piece 51' and the piece 56' to be small and for the course of oscillation between the pieces 51' and 55' to be limited, a multiplicity

P20918.A01

of oscillations, for example, as the subject walks or changes position of his/her body sufficing to generate the high pressure permitting supply to the chamber 61'.

In such an embodiment, as long as neither of the valves 64' and 66' is open, the two pieces 51' and 52' can move relative to one another only by a very short distance, and this thus ensures that the two skeletal elements to which they are anchored, for example two vertebrae, are maintained in the chosen position. The device for establishing high pressure can even be used to obtain a certain viscous damping of the small displacements permitted between the pieces 51' and 55'.

It will also be appreciated that having arranged the high-pressure and low-pressure valves 64', 66' on either side of the bellows 67', one or other of these valves can easily be actuated, according to choice, for example by a strong magnet placed on the skin in line with one of the valves in order to attract the ferromagnetic plunger such as 65' towards the left of the drawing and to open the valve.--

Please add the following Abstract appended on the next page:

--ABSTRACT OF THE DISCLOSURE

Skeletal implant of the type to be used for connecting at least two elements of the skeleton. The implant has at least two parts. Each of the parts is capable of being connected to one of the elements. The implant also uses at least one shock-absorbing device located between the at least two parts. The shock-absorbing device has an adjustable coefficient of resistance.--

P20918.A01


REMARKS

The Examiner is respectfully requested to enter the foregoing amendment prior to examination of the above-identified patent application.

Applicants have filed in the parent application a request for a (3) three month extension of time to render the filing of this continuation application timely. A copy of the Request for Extension of Time is enclosed herewith. Should the Request for Extension of Time become separated from the file of the parent application, Applicants hereby authorize the Commissioner to charge any fees necessary for establishing copendency between the parent application and this continuing application to deposit account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed number.

Respectfully submitted,
Fred ZACOUTO et al.


Reg. No. 45,294

Neil F. Greenblum
Reg. No. 28,394

January 9, 2002
GREENBLUM & BERNSTEIN, P.L.C.
1941 Roland Clarke Place
Reston, Virginia 20191
(703) 716-1191

Attachment: Appendix

APPENDIX

Changes to the paragraphs starting on page 63, line 31 to page 65, line 24:

Figure 64 shows a transverse cross section of an implant in a refined embodiment of the invention.

This implant 1' includes two end pieces 51' and 52' in the shape of a dolphin's head, having at their outermost parts holes or eyelets 53' and 54' through which it is possible to engage pedicle screws whose heads can be fixed rigidly in the area of the holes 53', 54'. Alternatively, these holes can be arranged in such a way as to permit an articulation of the head of the pedicle screw and thus an angular displacement between the end element and the screw which it bears.

Arranged between the two end pieces 51' and 52' there is a third piece 55' which is movable relative to the two ends. The piece 55' has a stirrup shape, of which one of the branches 56' supports a metal bellows 57' in a leaktight manner, the free end of which bellows is fixed in a leaktight manner against a piece 58' which is able to slide relative to the stirrup 55' and bears, in the manner of a journal, by virtue of a securing ring 45', but axially nonmovable relative to the piece 58', a threaded rod 59' which passes through a complementary tapped hole of the second branch 60' of the piece 55'. It will thus be appreciated that when the deformable element constituted by the bellows 57' deforms, the thus provoked axial displacement of the rod 59' integral with the upper end [3'] 52' entrains the rotation of this rod 59' in the fixed nut formed in the branch 60', and consequently a simultaneous movement of translation and rotation of the end piece 52' relative to the piece 60'.

Arranged inside the end piece 51' [there] is a leaktight cavity 61' which serves as a high-pressure chamber and in which there is a bellows 62' which is hermetically sealed and in which a vacuum has been established[, the]. The stiffness of this bellows, however, [being] is sufficient to ensure that it tends spontaneously to deploy and increase in volume even when it is surrounded by [the] high pressure prevailing in the chamber 61'. The chamber 61' communicates via a nondeformable conduit 63' with the inside of the metal bellows 57' by way of a high-pressure valve 64' lodged in the branch 56'[, this valve having]. This valve 64' has a tubular slide of soft iron 65' which is normally held back by a spring in the position closing off the passage towards the bellows 57'. It will be appreciated that when the plunger core 65' is brought into a position of opening counter to the valve spring, liquid at high pressure in the chamber 61' will run along the conduit 63' and enter the bellows 57'[, the]. The high pressure in the chamber 61' [being] is maintained by the concomitant deformation of the sealed bellows 62'. This inflow of liquid provokes the displacement of the piece 58' towards the branch 60' and, consequently, the distraction and rotation of the end piece 52' relative to the central piece 55'.

The inside of the bellows 57' also communicates, by way of a low-pressure valve 66' equipped with a plunger core identical to the core 65' situated in the piece 58', with the volume 67' surrounding the various pieces contained inside the deformable impermeable sleeve 68', at the two ends of which the ends of the pieces 51' and 52' emerge, this volume 67' forming the low-pressure volume. It will be appreciated that when the valve 66 is opened, liquid contained in the bellows 57' will exit and spread through the low-pressure volume 67', thus permitting a retraction or compression of the bellows 57' and a simultaneous rotation of the piece 52' in the opposite direction.

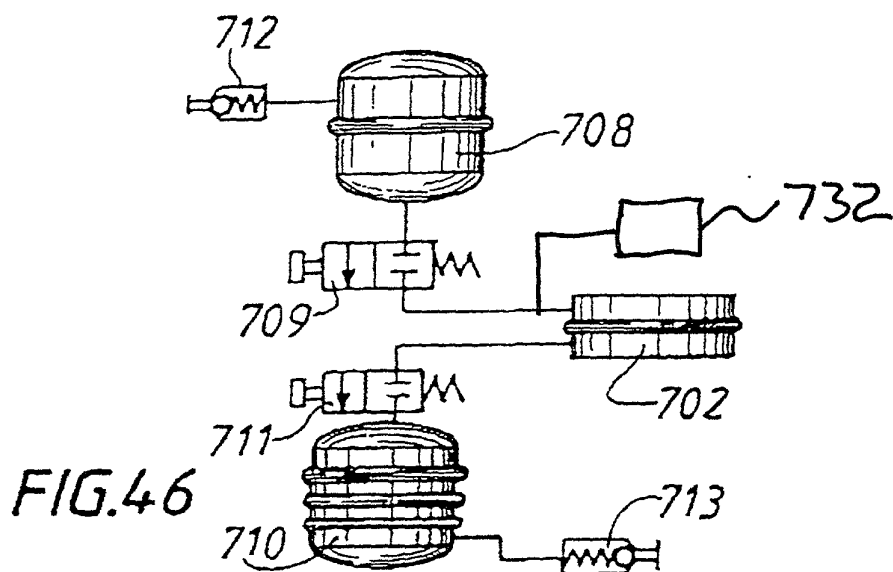
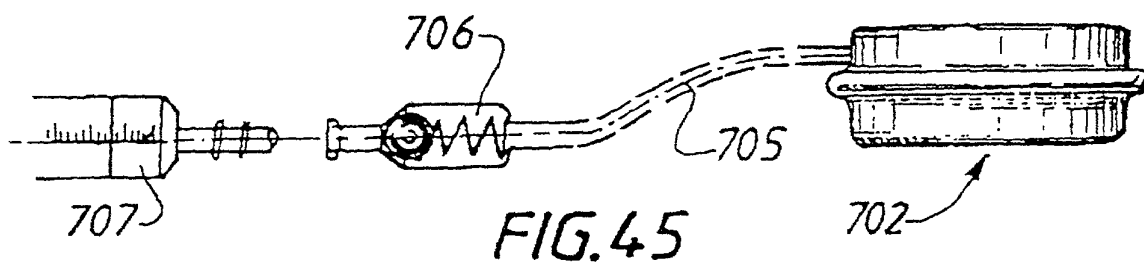
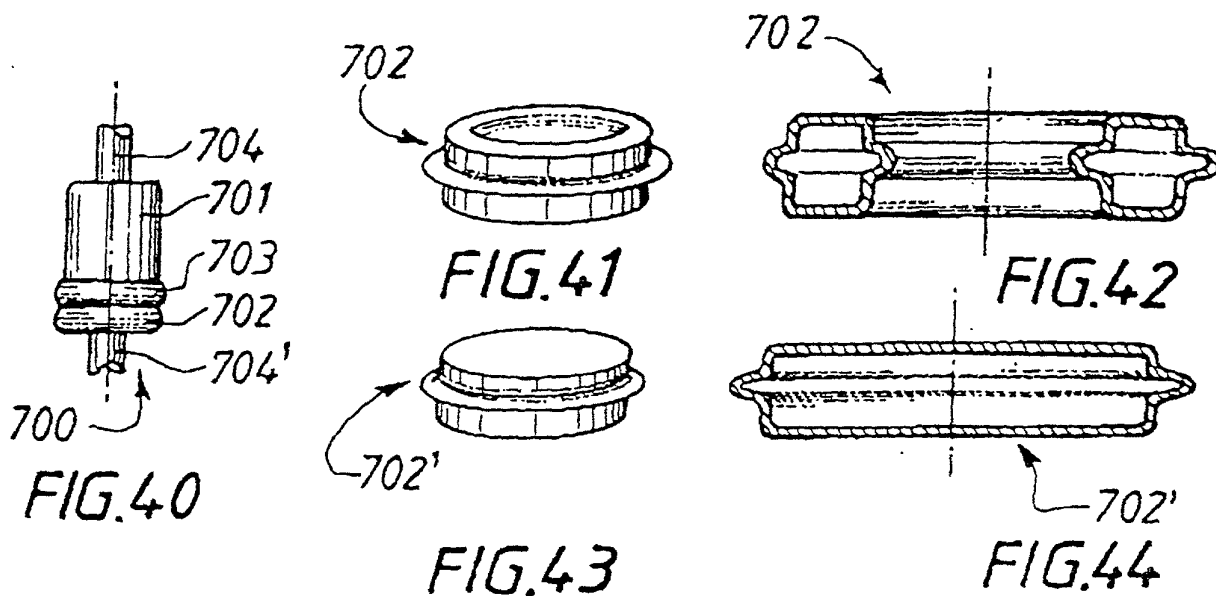
The high-pressure reservoir 61 is recharged by way of a metal bellows 69' which is of a diameter substantially smaller than that of the bellows 57' and which is interposed between the pieces 51' and 55'. When the pieces 51' and 55' move away from each other, this bellows 69' expands and aspires liquid from the low-pressure chamber 67' by way of a nonreturn valve 70'. By contrast, when the pieces 51' and 56' close together, the high pressure generated in the bellows 69' causes liquid at very high pressure to enter the high-pressure chamber 61' by way of a nonreturn valve 71'.

It is not necessary for the deformation of the bellows 69' to be of a great amplitude; on the contrary, it is preferable for the gap between the piece 51' and the piece 56' to be small and for the course of oscillation between the pieces 51' and 55' to be limited, a multiplicity of oscillations, for example, as the subject walks or changes position of his/her body sufficing to generate the high pressure permitting supply to the chamber 61'.

In such an embodiment, as long as neither of the valves 64' and 66' is open, the two pieces 51' and 52' can move relative to one another only by a very short distance, and this thus ensures that the two skeletal elements to which they are anchored, for example two vertebrae, are maintained in the chosen position. The device for establishing high pressure can even be used to obtain a certain viscous damping of the small displacements permitted between the pieces 51' and 55'.

It will also be appreciated that having arranged the high-pressure and low-pressure valves 64', 66' on either side of the bellows 67', one or other of these valves can easily be actuated, according to choice, for example by [means of] a strong magnet placed on the skin in line with one of the valves in order to attract the ferromagnetic plunger such as 65' towards the left of the drawing and to open the valve.

18/26



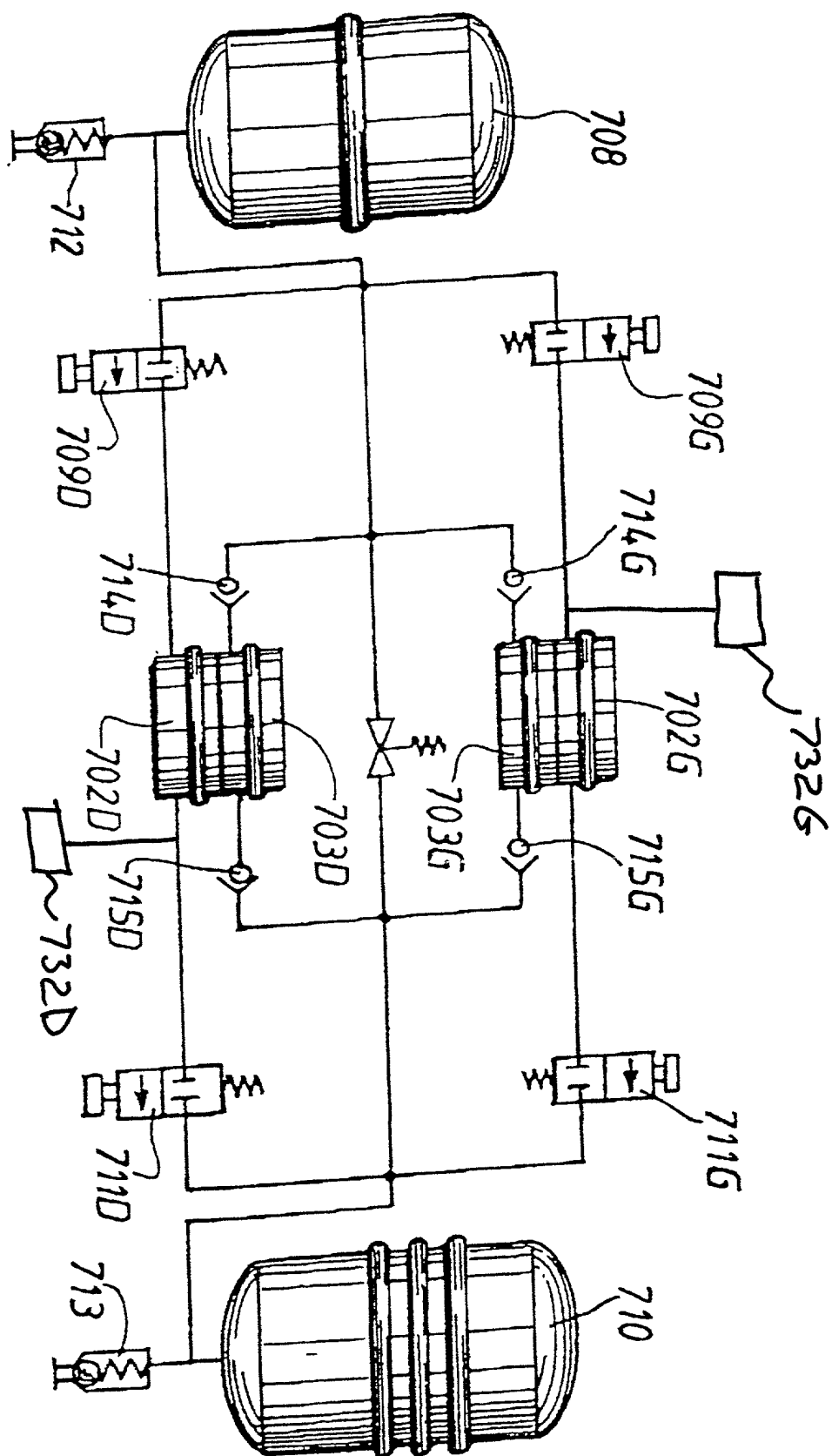


FIG. 47

19/26

10040429.010902

26/26

206010 62404001

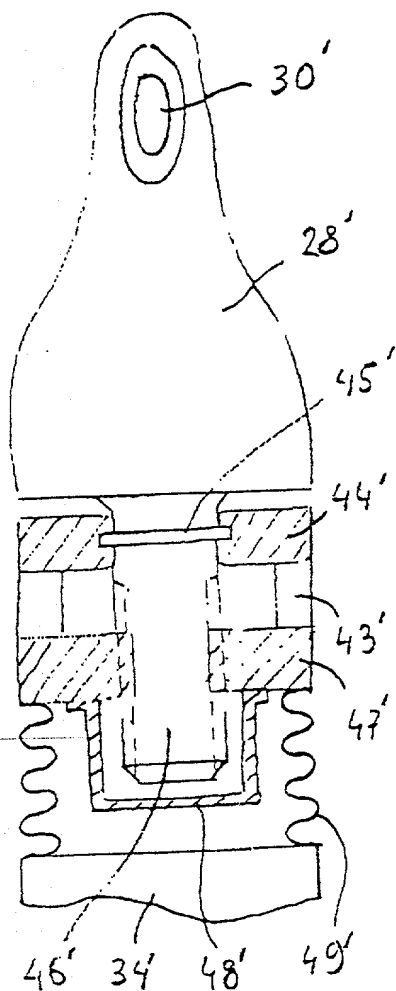


Fig 63

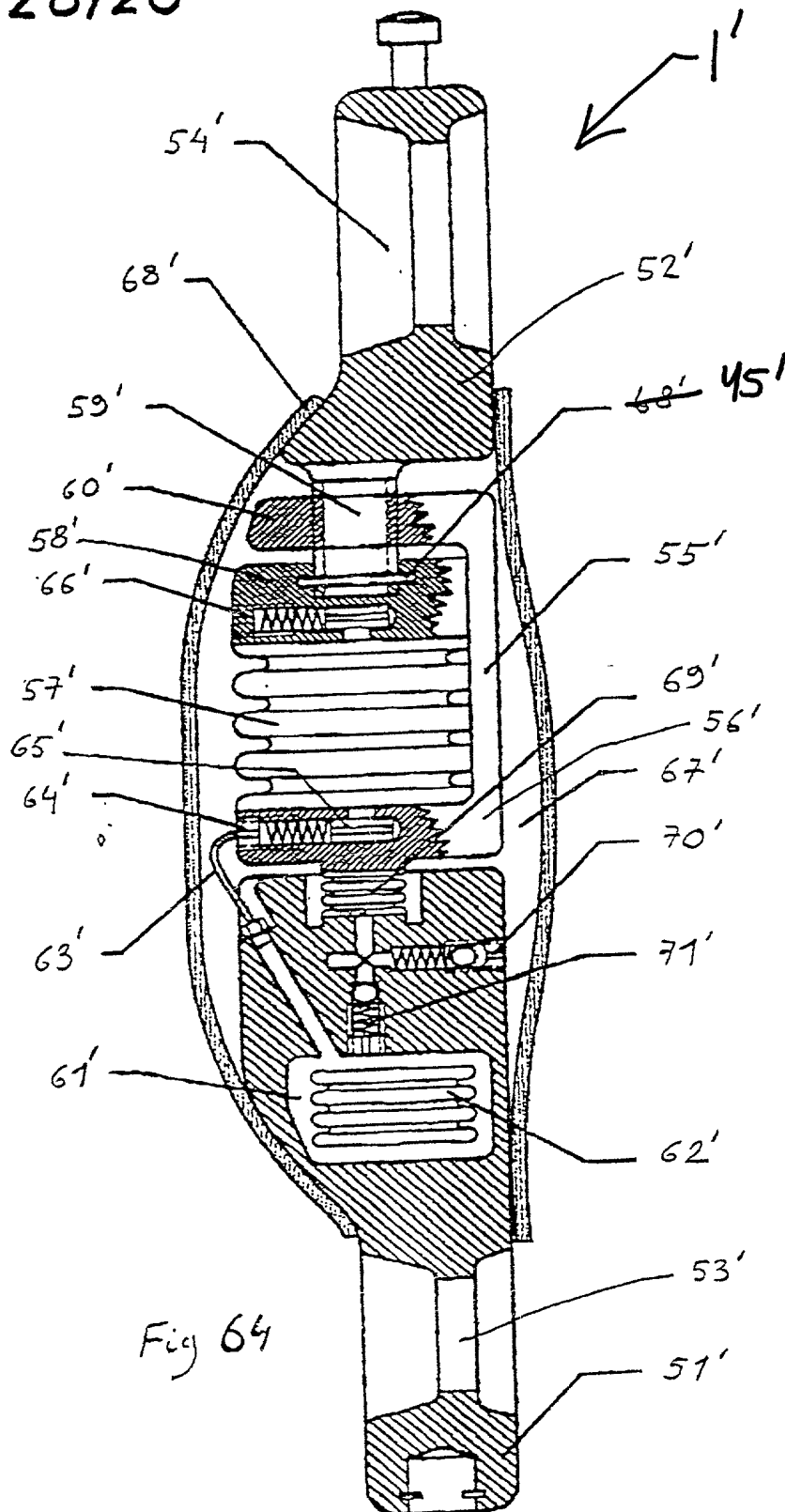


Fig 64